REMARKS

Claims 1-48 were presented at the time of filing with claims 33-48 cancelled by preliminary amendment; claims 1-32 were pending in the application. The claims are amended above with new claims 49 and 50 presented. Claims 1-32 and 49-50, therefore, are pending in the application.

The Action of March 26, 2008 requires election under 35 U.S.C. 121 and 372 between two groups of claims:

Group I (claims 1-9), drawn to a DNA vaccine composition comprising an isolated nucleic acid encoding an antigen selected from CD25, homologs, and fragments thereof operably linked to a transcription control sequence, and a pharmaceutically acceptable carrier, adjuvant, excipient, or diluent; and

Group II (claims 10-48), drawn to a method of preventing or inhibiting the development of a T-cell mediated pathology comprising administering a CD25 DNA vaccine.

According to the Office Action, the present invention lacks unity of invention in view of Kokuho *et al.* Applicants hereby provisionally elect the claims of Group I (claims 1-9) with traverse. Claim 1 is amended above to clarify that the recombinant construct used in practicing the present invention is a eukaryotic expression vector. Support for the amendment can be found in original claim 8. The claim, as amended, therefore, is directed to a DNA vaccine comprising a recombinant eukaryotic expression construct; Kokuho et al. does not teach the claimed composition.

Kokuho et al. describe cloning and determination of the chromosomal assignment of the porcine IL-2Rα gene. Two genomic segments of the IL-2Rα gene were isolated using a lambda phage library and independently cloned into phagemide vectors, namely pT7 and pBluescript II SK(-), which are designed for replication and selection in prokaryotic systems (specifically *E. coli*). In other words, the vectors of Kokuho et al., used for analyzing the sequence of the IL-

2Rα gene in prokaryotic systems, are not eukaryotic expression vectors suitable for expressing a protein of interest in a subject in need thereof.

While Kokuho *et al.* disclose a phagemide vector which contains a genomic segment of IL-2Rα including exon I and flanking upstream sequences that contain binding motifs for certain DNA-binding proteins, it is not demonstrated that these sequences are sufficient for effectively initiating and maintaining expression of the encoded sequence. In fact, Kokuho *et al.* do not show expression of any IL-2Rα-derived polypeptides. The publication merely suggests that the flanking upstream sequences may be important for "antigen-and IL-1-induced expression" (although the mechanism of IL-2Rα expression has not been elucidated) and that one of the binding motifs "contributed to the expression of reporter protein at higher extent" than one of the other binding motifs, in an experimental *in vitro* system (using mitogen-activated lymphoma cells; page 844, 5th paragraph).

In contradistinction, the present invention relates to DNA vaccines, in which a sequence encoding a CD 25 antigen (IL-2Rα, homologs or fragments thereof) is operably linked to suitable transcriptional control sequences, i.e. linked in a manner such that the molecule is able to be expressed in the host (the subject in need thereof). The present invention demonstrates, for the first time, such DNA vaccines which are able to provide sustained, long-term expression of the CD25 antigen in a manner and in an effective amount such that a beneficial immune response (an anti-ergotypic response) is formed in the vaccinated subject (see, for example, paragraphs [0016-0019], [0028], [0055], and Examples 1-8). None of these elements are taught by Kokuho *et al.*

Thus, it is respectfully submitted that Kokuho *et al.* do not disclose the invention of claim 1. The special technical features disclosed by the present invention, namely the use of DNA vaccines encoding CD25, homologs and fragments thereof (including SEQ ID NOs:2-4) for the treatment of T-cell mediated pathologies (including those listed on page 3 of the Office Action), therefore define a contribution over the prior art.

Election of a representative species of 1) CD25 polypeptide and 2) T-cell mediated autoimmune disease is also required. Applicants hereby elect SEQ ID NO. 2 as a representative species of CD25 polypeptide and rheumatoid arthritis as a representative species of T-cell mediated autoimmune disease. Claims 1-32 and 49-50 read on SEQ ID NO. 2; claims 10-15 and 17-27, 29-32 and 49-50 read on rheumatoid arthritis.

The Examiner is invited to contact Applicants' attorney at the telephone number given below if any further questions arise in connection with this Application.

Respectfully submitted,

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